K122633

BRANAN BMC MEDICAL CORP

FEB 7 2013

5.0 510(k) Summary

510(k) SUMMARY

This summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Establishment Name and Address

Branan Medical Corporation
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Irvine, CA 92618
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Date Prepared: August 24, 2012

Proprietary and Trade Name

ToxCup® Drug Screen Cup

Common Name

Qualitative Lateral Flow Immunoassay

Classification Panel

Toxicology (91)

Product Code and Regulation Number

Device	Panel	Product Code	Classification	Regulation Section	Description
THC	Toxicology (91)	LDJ	II	862.3870	Cannabinoid Test System
COC	Toxicology (91)	DIO	II	862.3250	Cocaine and Cocaine Metabolite Test System
OPI	Toxicology (91)	DJG	II	862.3650	Opiates Test System
MET	Toxicology (91)	DJC	II	862.3610	Methamphetamine Test System
AMP	Toxicology (91)	DKZ	II	862.3100	Amphetamine Test System
BZO	Toxicology (91)	JXM	II	862.3170	Benzodiazepine Test System, Over The Counter
BAR	Toxicology (91)	DIS	II	862.3150	Barbiturate Test System
MTD	Toxicology (91)	DJR	II	862.3620	Methadone Test System
BUPG	Toxicology (91)	DJG	II	862.3650	Opiates (Buprenorphine) Test System
TCA	Toxicology (91)	LFG	II	862.3910	Tricyclic Antidepressant Drugs Test System
MDMA	Toxicology (91)	DJC	II	862.3610	Methamphetamine (MDMA) Test System, Over The Counter
OXY	Toxicology (91)	DJG	II	862.3650	Opiates (Oxycodone) Test System, Over the Counter
PCP	Toxicology (91)	LCM	II	862.3100	Enzyme immunoassay Phencyclidine
PPX	Toxicology (91)	JXN	II	862.3700	Propoxyphene Test System

Device Classification

Class II

Substantially Equivalent Devices

K082898 – Amedica Home Drug Test Cup

Device Description

The ToxCup® Drug Screen Cup is based on the principle of highly specific immunochemical reactions between antigens and antibodies. It utilizes a competitive immunoassay procedure in which an immobilized drug conjugate competes with the drug present in urine for limited antibody binding sites. The ToxCup® Drug Screen Cup device consists of individual test strips, in single drug analyte cassette dip format and/or double analyte cassette dip format, assembled into separate chambers of a plastic insert and can detect up to 14 drugs in human urine at various cutoff concentrations. The presence of a color band at a specific test region indicates a negative result for that particular test. The absence of a color band at a specific test region indicates presumptive positive result for that particular test.

A control band at the control region should always appear regardless of the presence of the drug or its metabolites. The presence of the control band during testing serves as a built in control which indicates that the test has completed and is valid.

Intended Use

The ToxCup® Drug Screen Cup in single drug analyte cassette dip format and/or double analyte cassette dip format is an *in vitro* screening test for the rapid detection of multiple drugs and drug metabolites in human urine at or above the following cutoff concentration:

AMP	Amphetamine	500 ng/ml
BAR	Secobarbital	300 ng/ml
BUPG	Buprenorphine Glucuronide	10 ng/ml
BZO	Oxazepam	300 ng/ml
COC	Benzoylecgonine	150 ng/ml
MDMA	3,4-methylenedioxymethamphetamine	500 ng/ml
MET	Methamphetamine	500 ng/ml
MTD	Methadone	300 ng/ml
OPI	Morphine	300 ng/ml
OXY	Oxycodone	100 ng/ml
PCP	Phencyclidine	25 ng/ml
PPX	Propoxyphene	300 ng/ml
TCA	Nortipltyline	1000 ng/ml
THC	11-nor-Δ9-Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml

Indications for Use

The ToxCup® Drug Screen Cup is an *in vitro* screening test for the rapid detection of multiple drugs and drug metabolites in human urine at or above the following cutoff concentration:

AMP	Amphetamine	500 ng/ml
BAR	Secobarbital	300 ng/ml
BUPG	Buprenorphine Glucuronide	10 ng/ml
BZO	Oxazepam	300 ng/ml
COC	Benzoylecgonine	150 ng/ml
MDMA	3,4-methylenedioxymethamphetamine	500 ng/ml
MET	Methamphetamine	500 ng/ml
MTD	Methadone	300 ng/ml
OPI	Morphine	300 ng/ml
OXY	Oxycodone	100 ng/ml
PCP	Phencyclidine	25 ng/ml
PPX	Propoxyphene	300 ng/ml
TCA	Nortriptyline	1000 ng/ml
THC	11-nor-Δ9-Tetrahydrocannabinol-9-carboxylic acid	50 ng/ml

These tests provide visual qualitative results and are intended for *in vitro* diagnostic use only. The ToxCup® Drug Screen Cup is available in single drug analyte cassette dip format and/or double drug analyte cassette dip format. It is intended for prescription point-of-care and over-the-counter consumer use.

These tests provide only a preliminary test result and are the first step in a two-step process for detecting drugs of abuse in urine. The second step is confirming the results in a certified laboratory. For a quantitative result or to confirm preliminary positive results obtained by the ToxCup® Drug Screen Cup, a more specific alternative method such as Gas Chromatography/Mass Spectrometry (GC/MS) must be used. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when a preliminary positive result is indicated.

Predicate Device Comparison

Similarities		
Feature	**Subject Devices** (ToxCup® Drug Screen Cup)	**Predicate Device** (Amedica Home Drug Test Cup)
Intended Use	Screening Device	Screening Device
Matrix	Human Urine	Human Urine
Test Principle	Competitive immunoassay	Competitive immunoassay
Analytes and Cut-Off	THC 50ng/ml Morphine 300ng/ml Phencyclidine 25ng/ml Secobarbital 300ng/ml Benzodiazepines 300ng/ml Methadone 300ng/ml Oxycodone 100ng/ml MDMA 500ng/ml Nortriptyline 1000ng/ml	THC 50ng/ml Morphine 300ng/ml Phencyclidine 25ng/ml Secobarbital 300ng/ml Benzodiazepines 300ng/ml Methadone 300ng/ml Oxycodone 100ng/ml MDMA 500ng/ml Nortriptyline 1000ng/ml
Housing	Plastic lid and cup base	Plastic lid and cup base
Internal Procedural Controls	Control line	Control line
Intended User	Over The Counter Consumer	Over The Counter Consumer
Testing Method	Lateral Flow Immunoassay	Lateral Flow Immunoassay

Differences		
Feature	**Subject Devices** (ToxCup® Drug Screen Cup)	**Predicate Device** (Amedica Home Use Drug Test Cup)
Test Strip	Test up to 14 drugs	Test up to 12 drugs
Analytes and Cut-Off	Benzoylecgonine 150ng/ml Amphetamine 500ng/ml Methamphetamine 500ng/ml Buprenorphine Glucuronide 10ng/ml Propoxyphene 300ng/ml	Benzoylecgonine 300ng/ml Amphetamine 1000ng/ml Methamphetamine 1000ng/ml
Method Comparison Total % agreement	≥ 95%	≥ 93%
Storage	Sealed pouch at 15-30°C	Sealed pouch at 2-30°C
Intended User	Over The Counter Consumer and Prescription Point-of-Care use	Over The Counter Consumer
Reading Time	5 – 8 minutes	4 - 5 minutes

Test Summary:

Performance Specifications

The performance characteristics of the ToxCup® Drug Screen Cup were based on evaluations by the following analytical performance studies:

- Stability
- Optimal Read Time
- Precision/reproducibility
- Method Comparison
- Specificity and Interference
- Consumer Study

Conclusion

The performance characteristics studies performed demonstrate substantial equivalency between the ToxCup® Drug Screen Cup, the predicate kit Amedica Home Drug Test Cup.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 7, 2013

Branan Medical Corporation
c/o Olivia Chan
140 Technology Dr, Suite 400
Irvine, CA 92618

Re: k122633
Trade/Device Name: ToxCup® Drug Screen Cup
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: II
Product Code: LDJ, DIO, DJG, DJC, DKZ, JXM, DIS, DJR, LFG, LCM, JXN
Dated: January 18, 2013
Received: January 22, 2013

Dear Ms. Chan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k122633

Device Name: ToxCup® Drug Screen Cup

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(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Denise Johnson-Iyles -S
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Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) k122633

Indications for Use

510(k) Number (if known): k122633

Device Name: ToxCup® Drug Screen Cup

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Prescription Use ___X___ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use __X__. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

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Denise Johnson-lyles -S
2013.02.05 15:21:59 -05'00'

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

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